Antiosteoporotic drugs use reduction in Sicily during the years 2013-2016: a medical choice or an health policy measures consequence?

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Osteoporosis (OP) is a disorder of bone tissue, characterized by increased risk of low-trauma fractures. About 1/3 of females and 1/5 of males over 50 undergo to osteoporotic fractures with a great increase of morbidity and mortality. Bisphosphonates, selective estrogen receptor modulators (SERMs), strontium ranelate, teriparatide, and denosumab, together with calcium and vitamin D supplementation, have been shown to improve bone mass and to reduce significantly the risk of fractures in osteoporotic patients. In the last years, a wide increase of antiosteoporotic drugs (AODs) use was observed in Italy from 8.8 DDD/1000 inh. die in 2007 to 12.7 DDD/1000 inh. die in 2011. As a consequence, since 2011, the Italian Medicines Agency introduced a health-policy intervention (nota 79), revised in 2015, which restricted the refundability of AODs, according to specific conditions for which scientific evidence has been provided. Starting from year 2011, the increasing trend of AODs use stopped, maintaining a constant level of consumption. However, a high variability between regions was observed and Sicily amounted well above the national average, while in Veneto a lower drug use combine with lower risk of fractures. As a consequence, starting from year 2013, the Sicilian Regional department of Health introduced additional health-policy interventions to improve the AODs use.

The aim of the study was to analyze the AODs use in Sicily in the period 2013-2016, in the light of the National and Regional decrees.

Data were extracted from the “SFERA” project database in collaboration with the Sicilian Regional department of Health. All prescriptions of AODs (M05BX03 strontium ranelate, M05B* bisphosphonates, H05AA02 teriparatide, G03XC* SERMs, M05BX04 denosumab) in the years 2013-2016, were included. Drugs use was evaluated as DDD/1000 inh.die (95% CI) for each year. Analyses by single molecules and districts were performed.

In Sicily, the use of AODs decreased from 17.5 DDD/1000 inh.die in 2013 to 11.5 DDD/1000 inh.die in 2016, though higher than the national average. The same trend was observed in all districts. However, a high variability between districts was shown (6.3 - 15.6 range in year 2016). In particular, in 2015 year, the AODs use in Catania decreased more than 50% respect the prior year (from 15.8 to 7.6), with a difference of -38% from the regional average, concomitantly with regional specific checks on decrees respect. Bisphosphonates are the most used AODs over the years, without significant differences between districts, while, in accordance with national and regional health-policy interventions, the consumption of strontium ranelate fell in the year 2014. Although, Catania and Siracusa overall use of AODs is less than the other districts, they use from 5% to 8% more expensive daily dose molecules respect to the regional average.

At the moment, no data are available about the concomitant rate of osteoporotic fractures, nor data concerning adherence and persistence to AODs treatment. However, preliminary results

strongly suggest that AODs prescription are influenced more by regulatory interventions than clinical choices.